Supreme Court, U.S.
FILED
MAY 15 2006
OFFICE OF THE CLERK

No. 05-608

In the Supreme Court of the United States

MEDIMMUNE, INC., PETITIONER

v.

GENENTECH, INC., ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER

PAUL D. CLEMENT
Solicitor General
Counsel of Record
PETER D. KEISLER
Assistant Attorney General
THOMAS G. HUNGAR
Deputy Solicitor General
DEANNE E. MAYNARD
Assistant to the Solicitor General
SCOTT R. MCINTOSH
MARK R. FREEMAN
Attorneys
Department of Justice
Washington, D.C. 20530-0001
(202) 514-2217

JAMES A. TOUPIN
General Counsel
JOHN M. WHEALAN
Solicitor
MARY L. KELLY
JOSEPH G. PICCOLO
Associate Solicitors
United States Patent and Trademark Office
Alexandria, VA 22313

BEST AVAILABLE COPY

QUESTION PRESENTED

Whether Article III's grant of jurisdiction of "all Cases * * * arising under * * * the Laws of the United States," implemented in the "actual controversy" requirement of the Declaratory Judgment Act, 28 U.S.C. 2201(a), requires a patent licensee to refuse to pay royalties and commit material breach of the license agreement before suing to declare the patent invalid, unenforceable, or not infringed.

TABLE OF CONTENTS

Page

Interest of the United States 1
Statement 2
Summary of argument 8
Argument:
A patent licensee need not breach its license agreement in order to establish an "actual controversy" under Article III or the Declaratory Judgment Act 11
A. The "actual controversy" inquiry entails a fact-sensitive, case-by-case examination of the concreteness and reality of the asserted controversy 11
B. The court of appeals has erected an unwarranted obstacle to declaratory relief in patent cases 14
C. Petitioner's declaratory challenge to the Cabilly II patent presents an "actual controversy" 19
D. The judgment below cannot be justified by considerations of patent policy 23
Conclusion 30

TABLE OF AUTHORITIES

Cases:

Aetna Life Ins. Co. v. *Haworth*, 300 U.S. 227 (1937) 4, 11, 15, 19, 24
Altvater v. *Freeman*, 319 U.S. 359 (1943) ..... *passim*
American Sterilizer Co. v. *Sybron Corp.*, 526 F.2d 542 (3d Cir. 1975) 27
Babbitt v. *United Farm Workers Nat'l Union*, 442 U.S. 289 (1979) 16
Berg, In re, 140 F.3d 1428 (Fed. Cir. 1998) 7

Cases—Continued: Page

Blonder-Tongue Labs., Inc. v. *University of Ill. Found.*, 402 U.S. 313 (1971) 25, 27
BP Chems. Ltd. v. *Union Carbide Corp.*, 4 F.3d 975 (Fed. Cir. 1993) 6, 15
Cabilly v. *Boss*, 55 U.S.P.Q. 2d (BNA) 1238 (BPAI 1998) 4
Cardinal Chem. Co. v. *Morton Int'l, Inc.*, 508 U.S. 83 (1993) 25, 26
Cordis Corp. v. *Medtronic, Inc.*, 780 F.2d 991 (Fed. Cir. 1985), cert. denied, 476 U.S. 1115 (1986) 28
De Forest Radio Tel. Co. v. *United States*, 273 U.S. 236 (1927) 21
Edward Katzinger Co. v. *Chicago Metallic Mfg. Co.*, 329 U.S. 394 (1947) 25
Gen-Probe Inc. v. *Vysis, Inc.*, 359 F.3d 1376 (Fed. Cir.), cert. dismissed, 543 U.S. 941 (2004) ..... *passim*
Golden v. *Zwickler*, 394 U.S. 103 (1969) 13
Invitrogen Corp. v. *Biocrest Mfg., L.P.*, 424 F.3d 1374 (Fed. Cir. 2005) 27
Lake Carriers' Ass'n v. *MacMullan*, 406 U.S. 498 (1972) 15
Lear, Inc. v. *Adkins*, 395 U.S. 653 (1969) ..... *passim*
Maryland Cas. Co. v. *Pacific Coal & Oil Co.*, 312 U.S. 270 (1941) 11, 14, 15, 20, 21
Mercoid Corp. v. *Mid-Continent Inv. Co.*, 320 U.S. 661 (1944) 26
Nashville, Chattanooga & St. Louis Ry. v. *Wallace*, 288 U.S. 249 (1933) 3

Cases—Continued: Page

Pope Mfg. Co. v. *Gormully*, 144 U.S. 224 (1892) 28
Precision Shooting Equip. Co. v. *Allen*, 646 F.2d 313 (7th Cir.), cert. denied, 454 U.S. 964 (1981) 27
Public Utils. Comm'n v. *United States*, 355 U.S. 534 (1958) 15
Public Serv. Comm'n v. *Wycoff Co.*, 344 U.S. 237 (1952) 2, 3, 12, 13
Steffel v. *Thompson*, 415 U.S. 452 (1974) 9, 15, 16, 19
Teva Pharm. USA, Inc. v. *Pfizer, Inc.*, 395 F.3d 1324 (Fed. Cir. 2004), cert. denied, 126 S. Ct. 473 (2005) ... 15
Textron Lycoming Reciprocating Engine Div. v. *United Auto. Workers*, 523 U.S. 653 (1998) 13
United Pub. Workers v. *Mitchell*, 330 U.S. 75 (1947) ... 13
United States v. *Mitchell*, 463 U.S. 206 (1983) 23
Warner-Jenkinson Co. v. *Allied Chem. Corp.*, 567 F.2d 184 (2d Cir. 1977) 27
Wilton v. *Seven Falls Co.*, 515 U.S. 277 (1995) 29, 30

Constitution, statutes and rule:

U.S. Const. Art. III ..... *passim*
Tucker Act, 28 U.S.C. 1491 23
28 U.S.C. 2201(a) 2
35 U.S.C. 2(a) 1
35 U.S.C. 2(b)(8) 1
35 U.S.C. 282 28
35 U.S.C. 283 17
35 U.S.C. 284 17
35 U.S.C. 285 17

Statutes and rule—Continued:

Page

35 U.S.C. 301 *et seq.* 7
35 U.S.C. 301-307 (2000 & Supp. III 2003) 7
35 U.S.C. 311-318 (2000 & Supp. III 2003) 7
Fed. R. Civ. P. 57 2

Miscellaneous:

Federal Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003), *available at* <http://www.ftc.gov/os/2003/10/innovationrpt.pdf> 2, 26
H.R. Rep. No. 1264, 73d Cong., 2d Sess. (1934) 19
Patent of Cabilly, Application No. 90/007,542 (PTO Sept. 13, 2005), *available in* Public PAIR (PTO) 28
Restatement (Second) of Contracts (1981) 28
S. Rep. No. 1005, 73d Cong., 2d Sess. (1934) 3, 19
U.S. Dept. of Justice, *Report of the Department of Justice's Task Force on Intellectual Property* (2004), *available at* <http://www.usdoj.gov/olp/ip_task_force_report.pdf> 2
U.S. Dep't of Justice & Federal Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132 (1995), *available at* <http://www.usdoj.gov/atr/public/guidelines/0558.pdf> 2, 24

In the Supreme Court of the United States

No. 05-608

MEDIMMUNE, INC., PETITIONER

v.

GENENTECH, INC., ET AL.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONER

INTEREST OF THE UNITED STATES

This case presents the question whether a patent licensee in good standing may challenge the validity and scope of the licensed patent in federal court. The United States Patent and Trademark Office (PTO or Patent Office) is responsible for "the granting and issuing of patents," 35 U.S.C. 2(a), as well as for advising the President on domestic and international issues of patent policy, 35 U.S.C. 2(b)(8). Several federal agencies, including in particular the National Institutes of Health, are extensively engaged in the licensing of patented inventions to private entities, and the United States is also a licensee of various patents. In addition, this case implicates core concerns of the Federal Trade Commission and the Antitrust Division of the United States Depart-

ment of Justice, because intellectual property licensing can enhance consumer welfare by allowing for the efficient exploitation of intellectual property, but the existence of invalid patents in the marketplace can impede efficient licensing, hinder competition, and undermine incentives for innovation.[1] The government accordingly has a substantial interest in this Court's resolution of the question presented.

STATEMENT

1. The federal Declaratory Judgment Act (the Act) provides that "[i]n a case of actual controversy within its jurisdiction," any court of the United States "may declare the rights and other legal relations of any interested party," without regard to whether "further relief is or could be sought." 28 U.S.C. 2201(a); see Fed. R. Civ. P. 57. Integral to the Declaratory Judgment Act is the requirement of an "actual controversy." For years prior to Congress's adoption of the Act, "there were responsible expressions of doubt that constitutional limitations on federal judicial power would permit any federal declaratory judgment procedure." *Public Serv. Comm'n* v. *Wycoff Co.*, 344 U.S. 237, 241 (1952). In 1933, how-

---

[1] See generally Federal Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (2003) (*FTC Innovation Report*), *available at* <http:// www.ftc.gov/os/2003/10/innovationrpt.pdf> (last visited May 11, 2006); U.S. Dep't of Justice & Federal Trade Comm'n, *Antitrust Guidelines for the Licensing of Intellectual Property* (1995) (*DOJ/FTC Licensing Guidelines*), *reprinted in* 4 Trade Reg. Rep. (CCH) ¶ 13,132, at 20,733 (1995), *available at* <http://www.usdoj.gov/atr/public/guidelines/0558.pdf> (last visited May 11, 2006); see also U.S. Dep't of Justice, *Report of the Department of Justice's Task Force on Intellectual Property* (200-), *available at* <http://www.usdoj.gov/olp/ip_task_force_report.pdf> (last visited May 11, 2006).

ever, this Court held that a declaratory judgment action arising from the Tennessee state courts presented a justiciable case or controversy. *Nashville, Chattanooga & St. Louis Ry.* v. *Wallace*, 288 U.S. 249, 264-265 (1933). The *Wallace* Court emphasized that, notwithstanding the absence of a claim for injunctive or other coercive relief, the case presented a concrete legal dispute "of the kind which this court traditionally decides." *Id.* at 262. The "declaratory" nature of the remedy sought did not render the case nonjusticiable under Article III: "[T]he Constitution does not require that the case or controversy should be presented by traditional forms of procedure, invoking only traditional remedies. The judiciary clause of the Constitution defined and limited judicial power, not the particular method by which that power might be invoked." *Id.* at 264.

Congress enacted the Declaratory Judgment Act in the following year. See *Wycoff*, 344 U.S. at 241-242. The Senate committee report explained that the *Wallace* decision had dissipated the prevailing confusion between declaratory judgments and impermissible advisory opinions. See S. Rep. No. 1005, 73d Cong., 2d Sess. 5 (1934). Thus, "[t]he Federal bill specifically provides for declaratory adjudication only 'in cases of actual controversy.' That precludes hypothetical, academic, or moot cases. The words 'in cases of actual controversy' are designed to make certain what would be obvious even without them." *Ibid.*

This Court subsequently upheld the constitutionality of the Declaratory Judgment Act, highlighting both the breadth of the remedy thereby created and the limitations imposed by Article III on its administration: "The Declaratory Judgment Act must be deemed to fall within th[e] ambit of congressional power, so far as it

authorizes relief which is consonant with the exercise of the judicial function in the determination of controversies to which under the Constitution the judicial power extends." *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 240 (1937).

2. a. Petitioner MedImmune, Inc., is a biotechnology company whose principal product is Synagis®, a drug used in the prevention of respiratory tract disease in infants. Pet. App. 21a. In 1997, petitioner entered into a patent license agreement with respondents Genentech, Inc., a biotechnology company, and City of Hope, a nonprofit organization. *Id.* at 4a, 21a-22a, 28a-29a. That license agreement covered, among other things, a then-pending patent application, which eventually matured into U.S. Patent No. 6,331,415 (Cabilly II patent). *Id.* at 4a, 28a.[2]

In December 2001, the PTO issued the Cabilly II patent, which was assigned to respondents. Pet. App. 3a-4a, 21a-22a.[3] Shortly thereafter, respondents in-

---

[2] The Cabilly II patent is a continuation of respondents' Cabilly I patent, which the license agreement also covered. Pet. App. 2a.

[3] In 1990, the PTO declared an "interference" proceeding between the then-pending Cabilly II application and U.S. Patent No. 4,816,397 (Boss patent), which was owned by CellTech R&D, Ltd. Pet. App. 2a. In 1998, petitioner separately entered into a license agreement with CellTech for rights to the Boss patent. *Id.* at 4a. By obtaining licenses from both CellTech and respondents, petitioner ensured that it would have enforceable license rights irrespective of which side prevailed in the interference proceeding. Also in 1998, the PTO decided that the Boss patent had priority and administratively cancelled respondents' Cabilly II application. *Cabilly* v. *Boss*, 55 U.S.P.Q. 2d (BNA) 1238 (BPAI 1998). After respondents challenged that determination in federal court, they entered into a settlement agreement with Celltech which provided that the Cabilly II application was entitled to priority over the Boss

formed petitioner that they believed Synagis® was covered under the patent and, consequently, that sales of Synagis® were subject to royalties under the parties' 1997 license agreement. *Id.* at 4a. Petitioner initially denied that Synagis® infringed the Cabilly II patent, but soon began paying the demanded royalties, informing respondents that its payments were made "under protest and with reservation of all of our rights." J.A. 426; see J.A. 133. Petitioner maintains that it has continued to pay royalties and otherwise remain in good standing under its license agreement only to avoid the risk of an infringement action by respondents to enjoin sales of Synagis®, which petitioner claims accounts for over 80% of its revenues. J.A. 386-389. In 2003, petitioner filed this action for a declaratory judgment that the Cabilly II patent is invalid, unenforceable, and not infringed by Synagis®. Pet. App. 4a, 22a.

b. The district court dismissed petitioner's complaint for lack of jurisdiction based on the Federal Circuit's then-recent decision in *Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376, cert. dismissed, 543 U.S. 941 (2004). See Pet. App. 28a-31a. In *Gen-Probe*, the Federal Circuit applied its two-part test for determining whether there is an "actual controversy" under the Declaratory Judgment Act in patent cases, the first prong of which

---

patent. In return, Celltech obtained the right to share in all royalties that respondents received on the Cabilly II application and any resulting patents. The parties' settlement was conditioned on issuance of a court order vacating PTO's cancellation of the Cabilly II application and directing PTO to issue the Cabilly II patent. J.A. 334-335. At the joint request of the parties, the district court issued an order and entered judgment to that effect. J.A. 343-348. After further proceedings before the PTO, the PTO issued the Cabilly II patent. Pet. App. 3a-4a.

requires that the declaratory judgment plaintiff must labor under "a reasonable apprehension * * * that it will face an infringement suit." 359 F.3d at 1380.[4] *Gen-Probe* held that, as a matter of law, a patent licensee in good standing cannot establish an "actual controversy" with the patent owner, because the license agreement itself "obliterate[s] any reasonable apprehension of a lawsuit." *Id.* at 1381. Although the district court in this case suggested that it harbored "serious misgivings" about the wisdom of the *Gen-Probe* rule, it discerned "no relevant facts that distinguish this case" and concluded that it had no choice but to dismiss. Pet. App. 31a.[5]

3. The court of appeals affirmed, concluding that *Gen-Probe* was dispositive of the question of justiciability. Pet. App. 1a-9a.[6] The court of appeals distinguished *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969), on the ground

---

[4] The Federal Circuit's two-part test requires "both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Gen-Probe*, 359 F.3d at 1380 (quoting *BP Chems. Ltd.* v. *Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993)).

[5] The district court also rejected on the merits petitioner's antitrust claims, which included a claim that the interference settlement between respondents and Celltech (see note 3, *supra*) was collusive and fraudulent. See Pet. App. 22a; see also *id.* at 9a-15a.

[6] The Federal Circuit also rejected petitioner's remaining contentions on appeal, including a variety of challenges to the district court's disposition of petitioner's antitrust claims. Pet. App. 9a-17a. Those other issues are not before this Court. Judge Clevenger dissented from aspects of the court's holding on those remaining issues, but joined in full the court's dismissal of petitioner's declaratory judgment claims under the *Gen-Probe* rule. See *id.* at 17a-20a.

that "this case does not raise the question of whether patent invalidity is available as a defense to suit against a defaulting licensee—the licensee estoppel theory that was laid to rest in *Lear*—for there is no defaulting licensee and no possibility of suit." Pet. App. 6a. Rather, the court reasoned, "the issue here is not one of estoppel, but of availability of the declaratory judgment procedure." *Ibid.* In reaffirming the *Gen-Probe* rule, the court of appeals concluded that allowing petitioner to sue would "distort[] the equalizing principles that underlie the Declaratory Judgment Act." *Id.* at 7a. If petitioner's interpretation of the "actual controversy" requirement were to prevail, the Federal Circuit reasoned, the patentee, having contracted away its right to sue for infringement, would find itself "in continuing risk of attack on the patent whenever the licensee chooses—for example, if the product achieves commercial success—while the licensee can preserve its license and royalty rate if the attack fails." *Ibid.*[7]

---

[7] During the pendency of this case, a request was filed with the PTO for ex parte reexamination of the Cabilly II patent. See generally 35 U.S.C. 301 *et seq.* PTO reexamination is an administrative proceeding that may, but need not, result in the limitation or cancellation of some or all of the claims in a patent. See 35 U.S.C. 301-307 (2000 & Supp. III 2003) (ex parte reexaminations); see also 35 U.S.C. 311-318 (2000 & Supp. III 2003) (inter partes reexaminations). PTO granted the request and, in September 2005, provisionally rejected all of the claims of the Cabilly II patent as invalid for "obviousness-type double-patenting." *Patent of Cabilly*, Application No. 90/007,542, at 2-3 (PTO Sept. 13, 2005), *available in* Public PAIR (PTO); see *In re Berg*, 140 F.3d 1428, 1431-1432 (Fed. Cir. 1998) (explaining that "obviousness-type double patenting" is a judge-made doctrine that requires "rejection of an application claim when the claimed subject matter is not patentably distinct from the subject matter claimed in a commonly owned patent" in order "to prevent an unjustified extension of the term of the right

SUMMARY OF ARGUMENT

The Federal Circuit has adopted a restrictive test to determine the existence of an "actual controversy" in declaratory judgment cases that categorically precludes licensees in good standing from challenging patents under which they are licensed. Nothing in Article III, the Declaratory Judgment Act, or this Court's cases warrants such a special rule of justiciability for patent cases.

This Court has consistently held that whether a complaint alleges an "actual controversy" for purposes of the Declaratory Judgment Act presents a fact-sensitive issue that requires case-by-case determination. The question in each case essentially turns on whether the parties are involved in a substantial controversy that is sufficiently concrete and real that the court can resolve it through declaratory relief. When a plaintiff requests a declaration based on generalized facts and abstract legal claims, an actual controversy is lacking. But when the parties are truly adversarial, and the dispute is factually and legally concrete such that the requested declaration will definitely resolve a specific dispute, a justiciable controversy is present.

In patent cases, however, the Federal Circuit has "synthesi[zed]" this Court's contextual approach into a two-part test, which the court of appeals rigidly applies. Pet. App. 7a; *Gen-Probe Inc.* v. *Vysis, Inc.*, 359 F.3d 1376, 1379-1382, cert. dismissed, 543 U.S. 941 (2004). Under that test, a declaratory judgment plaintiff must

---

to exclude granted by a patent by allowing a second patent claiming an obvious variant of the same invention to issue to the same owner later"). The reexamination of the Cabilly II patent remains pending before the PTO.

have a "reasonable apprehension" of a suit for infringement by the patentee before a justiciable "case or controversy" will be recognized. In the court of appeals' view, therefore, a licensee in good standing cannot, as an Article III matter, challenge a patent under which it is licensed because the licensee can have no reasonable apprehension of an infringement suit.

That limitation on the availability of declaratory relief cannot be squared with this Court's cases or with the congressional purposes underlying the Act. As demonstrated by decisions of this Court involving pre-enforcement challenges to statutes, it is sufficient for a declaratory judgment plaintiff to demonstrate a genuine risk of enforcement and a reasonable likelihood that he would engage in the proscribed conduct if the threat were removed. A declaratory judgment plaintiff need not run the risks entailed in actually violating the law in order to make out an "actual controversy." See, *e.g.*, *Steffel* v. *Thompson*, 415 U.S. 452, 459, 475 (1974). Indeed, this Court has already rejected the proposition that a licensee's ongoing payment of patent royalties negates any justiciable dispute over the validity of the patent. *Altvater* v. *Freeman*, 319 U.S. 359 (1943). Yet the Federal Circuit's insistence on compliance with its two-part test requires a patent licensee to commit a material breach of its license agreement in order to create an "actual controversy." That result is contrary to the congressional purposes behind the Act, which was adopted to free parties of the requirement that they act at their peril on their own interpretation of their rights before being able to obtain a judicial construction of those rights.

Under a proper interpretation of the Declaratory Judgment Act, this case presents an "actual contro-

versy." Petitioner claims that respondents' Cabilly II patent is invalid and not infringed. Absent respondents' patent, and their claim that petitioner's principal product infringes that patent, petitioner would not be paying royalties to respondents on its sales of that product. The dispute between the parties is concrete, specific, and susceptible of judicial resolution, and the federal courts can therefore resolve it. The fact that the litigants have entered into a license agreement, under which petitioner currently is paying royalties, is simply not significant for Article III purposes, except to the extent that petitioner's payment of royalties provides concrete proof of the extent of the parties' dispute.

The court of appeals erred in suggesting that its judgment is supported by federal patent policy. Most fundamentally, policy considerations could not justify a departure from traditional Article III principles. In any event, considerations of patent policy actually point in favor of allowing licensees in good standing to challenge the validity of patents. Many patents are clearly valid and will not be subjected to challenge by licensees. But some patents are invalid, and there is a strong federal policy, as this Court has repeatedly recognized, in ridding the economy of such patents. Licensees, moreover, are often the sole or principal parties with the requisite knowledge and incentive to challenge them. And patent owners are far from defenseless; they have been granted a valuable legal monopoly, backed by a statutory presumption of validity and the threat of powerful legal remedies. It is not inequitable to force a patent holder to defend its patent.

ARGUMENT

A PATENT LICENSEE NEED NOT BREACH ITS LICENSE AGREEMENT IN ORDER TO ESTABLISH AN "ACTUAL CONTROVERSY" UNDER ARTICLE III OR THE DECLARATORY JUDGMENT ACT

Under the interpretation of the Declaratory Judgment Act adopted by the Federal Circuit in *Gen-Probe*, *supra*, and applied below, a patent licensee in good standing cannot bring a declaratory judgment action to challenge the patent under which it is licensed. That restrictive rule has no basis in Article III, the Declaratory Judgment Act, or this Court's jurisprudence. Under settled legal principles, the fact that a licensee is in good standing does not prevent the existence of an Article III "case or controversy" between the licensee and the patent holder with respect to the validity or construction of a licensed patent. And because the "actual controversy" requirement of the Declaratory Judgment Act authorizes declaratory relief in all cases and controversies cognizable under Article III, *Aetna Life Ins. Co.* v. *Haworth*, 300 U.S. 227, 241 (1937), the Act leaves no room for the creation of heightened obstacles to justiciability that apply only in actions under the federal patent laws.

A. The "Actual Controversy" Inquiry Entails A Fact-Sensitive, Case-By-Case Examination Of The Concreteness And Reality Of The Asserted Controversy

1. This Court has made clear that the determination whether an "actual controversy" exists for purposes of the Declaratory Judgment Act necessarily entails a fact-sensitive, case-by-case inquiry. As the Court explained in *Maryland Casualty Co.* v. *Pacific Coal & Oil Co.*, 312

U.S. 270, 273 (1941), "[b]asically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment."

In addition, as the Court noted in *Public Service Commission* v. *Wycoff Co.*, 344 U.S. 237 (1952), "the propriety of declaratory relief in a particular case will depend upon a circumspect sense of its fitness informed by the teachings and experience concerning the functions and extent of federal judicial power." *Id.* at 243. "The disagreement must not be nebulous or contingent but must have taken on fixed and final shape so that a court can see what legal issues it is deciding, what effect its decision will have on the adversaries, and some useful purpose to be achieved in deciding them." *Id.* at 244.

2. *Wycoff* illustrates the sort of claim that this Court has consistently held does *not* present an "actual controversy." A company that transported motion picture film in Utah sought a declaratory judgment, against the state's public utility commission, that the company's business constituted "interstate commerce." 344 U.S. at 239. The Court held that the company's claim was nonjusticiable, emphasizing the abstract nature of the requested declaration: "The complainant in this case does not request an adjudication that it has a right to do, or to have, anything in particular. It does not ask a judgment that the Commission is without power to enter any specific order or take any concrete regulatory step." *Id.* at 244. Rather, the Court explained, the company sought only "to establish that, as presently conducted, [its] carriage of goods between points within as well as without Utah is all interstate commerce. One naturally

asks, so what?" *Ibid.* There was no evidence of "any past, present, or threatened action by the Utah Commission" that would affect the company's business. *Id.* at 240-241. "If there is any risk of suffering penalty, liability or prosecution, which a declaration would avoid, it is not pointed out to us." *Id.* at 245.

Similarly, in *United Public Workers* v. *Mitchell*, 330 U.S. 75 (1947), the plaintiffs sought a declaratory judgment that certain provisions of the Hatch Act were unconstitutional. *Id.* at 82-83. The Court held that the plaintiffs' general assertion of a desire to engage in prohibited political activity did not create a justiciable controversy. *Id.* at 86-91. "We can only speculate as to the kinds of political activity the [plaintiffs] desire to engage in or as to the contents of their proposed public statements or the circumstances of their publication." *Id.* at 90. Absent a more concrete dispute, "[s]uch generality of objection is really an attack on the political expediency of the Hatch Act, not the presentation of legal issues," *id.* at 89, and thus beyond the competence of the federal courts to adjudicate. See, *e.g.*, *Textron Lycoming Reciprocating Engine Div.* v. *United Auto. Workers*, 523 U.S. 653, 660-661 (1998) (no "actual controversy" over voidability of collective bargaining agreement where there was no evidence that either the union or the employer "cared about" voidability); *Golden* v. *Zwickler*, 394 U.S. 103, 109 (1969) (no "actual controversy" in declaratory challenge to state law prohibiting anonymous handbilling in elections because the Congressman targeted by plaintiff's handbills had left Congress and was unlikely to again be a candidate).

By contrast, when the parties are truly adversarial, the dispute is concrete in both its factual and legal dimensions, and the requested declaration will definitively

settle the controversy, the Court has consistently held that relief is appropriate under the Declaratory Judgment Act. In *Maryland Casualty*, for example, an insurance company sought a declaratory judgment that it was not required either to defend litigation brought against the insured by the victim of an automobile accident, or to indemnify the insured if the victim prevailed. The insurance company named both the insured and the victim as defendants. The victim moved to dismiss on the ground that no "actual controversy" existed between himself and the insurance company, and the lower courts agreed. 312 U.S. at 271-272.

This Court reversed, observing that *if* the victim prevailed in his suit against the insured and the insured did not satisfy the resulting judgment, the victim would be entitled to proceed against the insurance company by supplementary process. *Maryland Cas.*, 312 U.S. at 273. That contingent possibility, the Court explained, established an "actual controversy" sufficient to warrant declaratory relief, especially given the potential, if the victim were not a party to the federal action, for conflicting judgments in state and federal court regarding the insurance company's obligations under the policy. *Id.* at 273-274. See, *e.g.*, *Steffel*, 415 U.S. at 459; *Lake Carriers' Ass'n* v. *MacMullan*, 406 U.S. 498, 506-508 (1972); *Public Utilities Comm'n* v. *United States*, 355 U.S. 534, 538-539 (1958); *Altvater*, 319 U.S. at 363-365; *Aetna Life*, 300 U.S. at 242-244.

B. The Court Of Appeals Has Erected An Unwarranted Obstacle To Declaratory Relief In Patent Cases

Despite this Court's more nuanced approach, the Federal Circuit has adopted an inflexible two-step test for declaratory relief in patent litigation. Pet. App. 7a-

8a. Under that test, "[t]here must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Gen-Probe*, 359 F.3d at 1380 (quoting *BP Chems. Ltd.* v. *Union Carbide Corp.*, 4 F.3d 975, 978 (Fed. Cir. 1993)); see Pet. App. 7a-8a. As the "reasonable apprehension" prong has been applied in the licensor-licensee context, moreover, the risk of litigation must be more than contingent (*e.g.*, contingent on the refusal to make the payments under the license)—the declaratory judgment plaintiff must face an actual, present apprehension of suit for an injunction, damages, or other coercive relief. See, *e.g.*, *id.* at 5a-6a. In other words, the declaratory judgment plaintiff must already have taken steps that expose it to a risk of suit.[8]

Proof that the declaratory judgment plaintiff labored under a reasonable anticipation of suit is certainly a valid means of establishing that an "actual controversy" exists. But the Federal Circuit effectively treats its two-step test as an all-encompassing restatement of the "actual controversy" requirement in the patent context, and essentially requires a breach before allowing a licensee to sue. See, *e.g.*, Pet. App. 7a-8a; *Gen-Probe*, 359 F.3d at 1379-1380. As a result, the Federal Circuit's test artificially and impermissibly limits the broad power of the federal courts to hear and decide concrete disputes be-

---

[8] In at least one recent case, moreover, the court of appeals added the further gloss that an infringement suit by the patentee must be "imminent." See *Teva Pharm. USA, Inc.* v. *Pfizer, Inc.*, 395 F.3d 1324, 1334 (Fed. Cir. 2004), cert. denied, 126 S. Ct. 473 (2005).

tween adverse parties in appropriate declaratory judgment actions.

1. This Court has never suggested that a declaratory judgment plaintiff must face a present risk of suit for coercive relief before an Article III case or controversy will exist. To the contrary, the Court has specifically refused to equate "actual controversy" with the existence of an accrued cause of action for a coercive remedy. In the context of pre-enforcement challenges to criminal statutes, for example, Article III requires a declaratory judgment plaintiff to demonstrate that he faces a "genuine threat of enforcement" if he violates the proscription in question, *Steffel*, 415 U.S. at 475, and that he would be reasonably likely to engage in the proscribed conduct without the threat of enforcement, *id.* at 459. If that showing is made, however, the Constitution does not further require the plaintiff to "expose himself to actual arrest or prosecution" before a declaratory judgment will issue. *Ibid.*; see *Babbitt* v. *United Farm Workers Nat'l Union*, 442 U.S. 289, 301-302 (1979) (allowing plaintiffs to bring challenge to statutory prohibition on false or deceptive speech about agricultural products without a showing that plaintiffs had already violated the prohibition). Indeed, forcing the putative declaratory judgment plaintiff to take the step that actually exposes him to liability would frustrate the purposes of the Declaratory Judgment Act. See pp. 18-19, *infra*. Yet the court below, applying its "reasonable apprehension" test, essentially obligates patent licensees to take such a step in order to create a justiciable controversy, requiring the licensee to "materially breach[] its license," *Gen-Probe*, 359 F.3d at 1382, and thereby subject itself to the risk of an injunction and an award of

damages (potentially including treble damages and attorneys fees). See 35 U.S.C. 283, 284, 285.

There is no justification for imposing a heightened standard for justiciability in the patent context. In fact, this Court has expressly rejected the argument that a licensee's ongoing payment of patent royalties negates any justiciable dispute over the validity of the patent. In *Altvater*, *supra*, the patentees brought suit against two of their licensees to compel specific performance of the territorial restrictions in their license agreement. The licensees filed a counterclaim seeking, *inter alia*, a declaratory judgment that the underlying patents were invalid. 319 U.S. at 360-361. The licensees continued to pay royalties to the patentees "under protest," however, based both on the license agreement itself and on an injunction that the patentees had obtained in earlier litigation against the same licensees. *Id.* at 361-362. As in this case, the licensees explicitly sought to retain the right to perform under the license agreement in the event the patents were held valid and the agreement binding. See *id.* at 361. And as in this case, the patentees opposed the declaratory judgment on the ground that "so long as [the licensees] continue to pay royalties, there is only an academic, not a real controversy, between the parties." *Id.* at 364.

The Court rejected that argument and held the declaratory judgment claim justiciable, explaining that "[t]he fact that royalties were being paid did not make this a 'difference or dispute of a hypothetical or abstract character.'" *Altvater*, 319 U.S. at 364 (citation omitted). Rather, "[a] controversy was raging," and "[t]hat controversy was 'definite and concrete, touching the legal relations of parties having adverse legal interests.'" *Ibid.* To be sure, "[r]oyalties were being demanded and

royalties were being paid. But they were being paid under protest and under the compulsion of an injunction decree." *Id.* at 365. Indeed, "[i]t was to lift the heavy hand of that tribute from the business that the counterclaim was filed. Unless the injunction decree were modified, the only other course was to defy it, and to risk not only actual but treble damages in infringement suits." *Ibid.* (footnote omitted).

The court of appeals in *Gen-Probe* attempted to distinguish *Altvater* on the ground that the licensees' ongoing royalty payments in *Alvater* were not merely required by contract, but compelled by injunction. See 359 F.3d at 1381-1382. From the perspectives of Article III and the Federal Circuit's own test, there is no significance to that distinction. The licensees in *Altvater* would have failed the Federal Circuit's "reasonable apprehension of suit" test just as petitioner did. Yet the Court had little difficulty concluding that there was an "actual controversy" between the parties. That "actual controversy" flowed not from the injunction but from the dispute between the parties, "the heavy hand of * * * tribute," and the prospect of treble damages from infringement, all of which are present here.[9]

2. The court of appeals' test is inconsistent with the fundamental purposes of the Declaratory Judgment Act. It is clear that Congress did not intend the "actual controversy" requirement to obligate the declaratory judgment plaintiff to expose itself to a suit for coercive relief.

---

[9] Nothing in *Altvater* indicates that the injunctive nature of the licensees' royalty obligation was dispositive. To the contrary, the Court expressly contemplated that the licensees had the option of ceasing payments and thereby risking "not only actual but treble damages in infringement suits." 319 U.S. at 365. Petitioner's options here are not meaningfully different.

To the contrary, one of the oft-stated purposes of the Declaratory Judgment Act was to enable parties to obtain a declaration of their rights in a dispute without needlessly exposing themselves to an injunction or liability for damages.

Congress recognized that, under the pre-Act state of affairs, it was "often necessary to break a contract or a lease, or act upon one's own interpretation of his rights when disputed, in order to present to the court a justifiable controversy." S. Rep. No. 1005, *supra*, at 3. The Act addressed that dilemma by "enabl[ing] disputes arising out of written instruments, or otherwise, to be adjudicated without requiring a destruction of the status quo." *Id.* at 6; see H.R. Rep. No. 1264, 73d Cong., 2d Sess. 2 (1934) ("If the meaning of a contract is controverted, for example, it may be needless to break it in order to obtain authoritative construction of the instrument, thus saving time and cost."); see also *Steffel*, 415 U.S. at 466-468 (observing that an express purpose of the Declaratory Judgment Act was to permit pre-enforcement challenges to unconstitutional state criminal statutes). The court of appeals' view that a party to a licensing agreement must breach the agreement before maintaining a declaratory judgment action in the patent context is simply irreconcilable with Congress's purposes in adopting the Act.

C. Petitioner's Declaratory Challenge To The Cabilly II Patent Presents An "Actual Controversy"

Petitioner's challenge to the validity of the Cabilly II patent and its claim of non-infringement comprise "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to

warrant the issuance of a declaratory judgment." *Maryland Cas.*, 312 U.S. at 273.

1. In this case, the parties' interests are adversarial, the factual and legal dimensions of their dispute are clear, and a declaratory judgment would conclusively resolve the issues that divide them. Petitioner is making royalty payments to respondents under a patent that petitioner claims is either invalid or not infringed by its Synagis® product (or both). Pet. App. 4a, 28a-29a. Respondents insist that the Cabilly II patent covers petitioner's sales of Synagis® and that, under the terms of the licensing agreement, petitioner must pay them royalties. *Id.* at 4a; J.A. 419-420. Although petitioner agreed, under implicit threat of suit (*ibid.*), to pay royalties after the issuance of the Cabilly II patent, it did so with the explicit warning that its payments were made "under protest and with reservation of all of our rights." J.A. 426; see J.A. 133. Furthermore, respondents do not dispute that, if petitioner had not begun paying royalties, it likely would have brought suit for infringement, breach of contract, or both.

Those facts amply demonstrate the existence of a concrete "case or controversy" under the standards enunciated by this Court for purposes of Article III and the Declaratory Judgment Act. Petitioner's contention that the Cabilly II patent is invalid and not infringed by Synagis® is wholly unlike the abstract complaints that this Court held unfit for judicial resolution in *Wycoff*, *Mitchell*, and similar cases. Indeed, respondents have not identified any respect in which this case is actually unfit for resolution by declaratory judgment, apart from the fact that there is a license agreement between the parties covering the Cabilly II patent.

2. There is no basis for concluding that the existence of a license agreement somehow transforms what would otherwise be an "actual controversy" into a non-justiciable request for an advisory opinion. For purposes of Article III and the Declaratory Judgment Act, it is simply immaterial that petitioner has entered a license agreement in order, *inter alia*, to avoid potential liability for infringement and has not breached its license agreement with respondents. What matters instead is whether there is a genuine dispute between the parties that is sufficiently concrete, specific, and substantial to warrant judicial intervention. *Maryland Cas.*, 312 U.S. at 273. If that standard is satisfied, as it is here, the fact that the parties previously agreed to enter into a licensing arrangement does not negate the existence of a controversy "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Ibid.* Indeed, when a licensing agreement involves royalty payments from a licensee that disputes the validity of the patent, the agreement is better understood as evidence of (not an obstacle to) a concrete controversy.[10]

The Federal Circuit's contrary rule, if applied consistently, would produce still further incongruous results. The requirement of a "reasonable apprehension of suit" would generally prevent non-breaching licensees from

---

[10] Even if one views a license as an agreement by the *patentee* not to sue for infringement, see Pet. App. 7a; *De Forest Radio Tel. Co.* v. *United States*, 273 U.S. 236, 242 (1927), the license agreement is not a concession by the *licensee* of the validity or applicability of the patent, much less an agreement not to sue. *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969). The licensee has entered into the agreement against the inherently coercive backdrop of the presumption of validity and the powerful remedies afforded by the law to the patentee. See *Altvater*, 319 U.S. at 365.

seeking court action to resolve even those contractual disputes beyond validity and infringement. For instance, if petitioner had claimed that the license only obligated it to pay royalties at rate *A*, and respondents believed the license in fact obligated petitioner to pay royalties at higher rate *B*, that would seem to be a paradigmatic scenario for use of the declaratory judgment remedy. But, under the Federal Circuit's "reasonable apprehension of suit" test, as long as petitioner was paying respondents the higher rate *B*, even if under protest, it apparently could not bring a declaratory judgment action to settle that very real dispute.

The Federal Circuit's requirement of an open breach is antithetical to the purposes of the Declaratory Judgment Act and has no basis in any constitutional or statutory limitation on the power of federal courts. This Court's conclusion in *Altvater* applies with equal force here: Petitioner continues to pay royalties, but seeks a declaratory judgment to "lift the heavy hand of that tribute" from its business. 319 U.S. at 365. Like the licensees in *Altvater*, petitioner's only other choice is to breach the license agreement and "risk not only actual but treble damages in [an] infringement suit[ ]," *ibid.*, together with an injunction against the sale of a product that accounts for over 80% of its revenues. And because there is little doubt, based on respondents' immediate demand for royalties after the issuance of the Cabilly II patent, that petitioner faced a genuine risk of suit if it ceased paying royalties, all of the requirements of Article III justiciability are met. "It was the function of the

Declaratory Judgment Act to afford relief against such peril and insecurity." *Ibid.*[11]

D. The Judgment Below Cannot Be Justified By Considerations Of Patent Policy

The Federal Circuit found support for its strict interpretation of the "actual controversy" requirement in the policies of the federal patent laws. Pet. App. 7a; see *Gen-Probe*, 359 F.3d at 1382. The court stressed the "inequity" it believed would result from a rule that allowed a licensee to challenge the patent under which it is licensed, while "the patent owner, having contracted away its right to sue, is in continuing risk of attack on the patent whenever the licensee chooses—for example, if the product achieves commercial success." Pet. App. 7a. Such inequity must be avoided, the court of appeals stated in *Gen-Probe*, because it would needlessly "discourage patentees from granting licenses." 359 F.3d at 1382.

Considerations of patent policy, however, could not justify creation of a patent-specific test that is more rigorous than the constitutional and statutory standards that determine the existence of a justiciable case or controversy in all other contexts. And in any event, the applicable policy considerations (to the extent they are relevant at all) point in the opposite direction. While patent licensing in general should be encouraged be-

---

[11] When the licensor is the United States, however, declaratory remedies may nevertheless be unavailable for other jurisdictional reasons. For example, although a variety of federal agencies license patented technologies to the private sector, claims by licensees against the United States under such agreements would generally have to be brought pursuant to the Tucker Act, which normally does not authorize declaratory relief. See 28 U.S.C. 1491; *United States v. Mitchell*, 463 U.S. 206, 216 n.15 (1983).

cause it allows the efficient exploitation of technology and promotes competition and innovation, see *DOJ/FTC Licensing Guidelines* 4-6, public policy strongly favors ridding the economy of invalid patents, which impede efficient licensing, hinder competition, and undermine incentives for innovation.

1. As an initial matter, the standards governing the "actual controversy" inquiry do not vary depending on a court's assessment of the policy considerations at issue. This Court has made clear that those standards are derived from Article III itself, and that the Declaratory Judgment Act is operative "in respect to controversies which are such in the constitutional sense." *Aetna*, 300 U.S. at 240. Considerations of patent policy cannot change the constitutional analysis, and so the court of appeals' conclusion logically precludes Congress from responding based on its own assessment of patent policy. By declaring that "the *jurisdictional requirements* of a declaratory action *are not met* when royalties are fully paid to the licensor and there is no ground on which the licensor can cancel the license or sue for infringement," Pet. App. 6a (emphasis added), the court of appeals effectively placed the problem beyond the power of Congress to redress. If the court's judgment were properly grounded in Article III that consequence would be unavoidable. But Article III poses no obstacle to suits like this, and considerations of patent policy are properly evaluated by Congress, not by the courts in construing the Act's "actual controversy" requirement, which applies equally to all manner of disputes.

2. In any event, the Federal Circuit also erred in its assessment of the applicable policy considerations. The court's desire to protect patentees from the burden of defending their patents against litigation challenges

cannot be reconciled with *Altvater* (see pp. 17-18, *supra*) or *Lear, Inc.* v. *Adkins*, 395 U.S. 653 (1969). To be sure, as the court of appeals recognized, *Lear* involved the substantive doctrine of "licensee estoppel," not the "actual controversy" requirement of the Declaratory Judgment Act. Pet. App. 5a-6a. But *Lear*'s holding is based on the strong federal policy favoring "full and free competition in the use of ideas which are in reality a part of the public domain," 395 U.S. at 670, a point that this Court has repeatedly underscored. See, *e.g.*, *Cardinal Chem. Co.* v. *Morton Int'l, Inc.*, 508 U.S. 83, 100-101 (1993) (noting the "importance to the public at large of resolving questions of patent validity"); *Blonder-Tongue Labs., Inc.* v. *University of Ill. Found.*, 402 U.S. 313, 349-350 (1971) (describing the Court's "consistent view" that "the holder of a patent should not be insulated from the assertion of defenses and thus allowed to exact royalties for the use of an idea that is not in fact patentable or that is beyond the scope of the patent monopoly granted"); *Edward Katzinger Co.* v. *Chicago Metallic Mfg. Co.*, 329 U.S. 394, 400 (1947) (noting the "necessity of protecting our competitive economy by keeping open the way for interested persons to challenge the validity of patents which might be shown to be invalid").

In light of those precedents, the court of appeals was wrong to suggest that it would be "inequit[able]" to permit licensees who otherwise satisfy the requirements for declaratory relief to challenge the validity of the patents under which they are licensed. Pet. App. 7a. Indeed, the Declaratory Judgment Act reflects a general judgment that it is equitable (and indeed desirable) to allow contracting parties with a dispute regarding their agreement to litigate the dispute without the necessity of an open breach. There is no basis for a special rule for pat-

ent licensees. To the contrary, when a justiciable controversy is present under the general principles of Article III, equitable considerations will normally counsel in favor of permitting such challenges in the patent context, because "[i]t is the public interest which is dominant in the patent system." *Mercoid Corp.* v. *Mid-Continent Inv. Co.*, 320 U.S. 661, 665 (1944). And, as *Lear* observed, "[l]icensees may often be the only individuals with enough economic incentive to challenge the patentability of an inventor's discovery." 395 U.S. at 670.

The Federal Circuit's specific concerns about discouraging the licensing of patents and encouraging gamesmanship by licensees, see Pet. App. 7a; see also *Gen-Probe*, 359 F.3d at 1382, are overstated. Many patents are clearly valid, and thus are unlikely to be challenged. Many patent holders affirmatively desire to license their patents, and many licensees enter licensing agreements with no intent of challenging the validity of the licensed patent. Patent litigation is extremely expensive and lengthy, and often both sides will have an incentive to avoid that expense. See, *e.g.*, *Cardinal Chem.*, 508 U.S. at 99; *FTC Innovation Report*, Exec. Summary 7-8 & n.25 (noting, in 2003, that "[a] biotechnology case, for example, can cost between five and seven million dollars and take two or three years to litigate"). Moreover, there will often be other considerations, such as the existence of cross-licensing arrangements or the desire to preserve valuable business relationships, that will militate against initiation of costly and disruptive patent litigation by licensees. Indeed, the Federal Circuit's concerns are further undercut by the fact that before the creation of the Federal Circuit, case law in a number of circuits supported the notion

that licensees did not have to breach or terminate their license agreements in order to bring a declaratory action.[12]

In any event, to the extent that rejecting the *Gen-Probe* rule does encourage licensees to challenge patents through litigation, that result furthers—rather than hinders—good patent policy. As this Court has recognized, if licensees "are muzzled, the public may continually be required to pay tribute to would-be monopolists without need or justification." *Lear*, 395 U.S. at 670. The Federal Circuit's rule engenders precisely that result, and thus cannot be justified on policy grounds.

3. Application of traditional "case or controversy" principles in the patent context does not leave patent owners defenseless. See *Blonder-Tongue*, 402 U.S. at 335 (noting that "patentees are heavily favored as a class of litigants by the patent statute"). The Patent Office has conferred upon the patentee a valuable property right that is "buttressed by the presumption of validity which attaches to his patent." *Lear*, 395 U.S. at 670; see 35 U.S.C. 282. Indeed, the Federal Circuit has held that "[o]vercoming the presumption requires a showing of facts proved by clear and convincing evidence." *Invitrogen Corp.* v. *Biocrest Mfg., L.P.*, 424 F.3d 1374, 1378 (Fed. Cir. 2005). This Court has thus recognized that it is not "unfair to require a patentee to defend the Patent Office's judgment when his licensee places the question in issue." *Lear*, 395 US. at 670.

---

[12] See *Precision Shooting Equip. Co.* v. *Allen*, 646 F.2d 313, 314-319 (7th Cir.), cert. denied, 454 U.S. 964 (1981); *Warner-Jenkinson Co.* v. *Allied Chem. Corp.*, 567 F.2d 184, 187-188 & n.4 (2d Cir. 1977); *American Sterilizer Co.* v. *Sybron Corp.*, 526 F.2d 542, 545-547 (3d Cir. 1975).

In addition, a patent owner may be able to negotiate license provisions that anticipate and ameliorate the effects of the filing of a declaratory judgment action by a licensee. This Court has held that a patentee cannot require a licensee to abandon forever its right to challenge a patent, see *Pope Mfg. Co.* v. *Gormully*, 144 U.S. 224, 232-237 (1892), and that a licensee who successfully challenges a patent cannot be required to pay royalties during the pendency of the challenge, see *Lear*, 395 U.S. at 673-674. But a licensor may be able to make the filing of a declaratory judgment action a basis for terminating the license, changing the royalty rate to a specified higher rate, or otherwise adjusting the pre-challenge terms. Cf., *e.g.*, Restatement (Second) of Contracts § 356(1) (1981) ("Damages for breach by either party may be liquidated in the agreement but only at an amount that is reasonable in light of the anticipated or actual loss caused by the breach and the difficulties of proof of loss."). While the enforceability of such provisions is an open question in light of the strong public policy favoring patent challenges as reflected in *Pope* and *Lear*, those decisions do not necessarily entitle a licensee both to challenge the licensed patent and to retain all the benefits of his license agreement, if the agreement expressly provides otherwise. Cf. *Cordis Corp.* v. *Medtronic, Inc.*, 780 F.2d 991, 995 (1985) (explaining the Federal Circuit's view that *Lear* "*does* permit a licensee to cease payments due under a contract while challenging the validity of a patent. It *does not* permit the licensees to avoid facing the consequences that such an action would bring."), cert. denied, 476 U.S. 1115 (1986). In addition, a would-be licensee that makes clear that it disputes the validity or applicability of the patent may not receive the same terms as other licens-

ees. Patentees concerned about potential litigation could, for example, require prospective licensees to purchase a fully paid-up license. Therefore, the Federal Circuit's assumption that permitting suits like this will necessarily allow licensees to lock in a favorable rate and then sue may be unfounded.

4. For the foregoing reasons, the Federal Circuit's patent-policy concerns cannot justify its conclusion that declaratory actions by licensees in good standing are nonjusticiable under Article III. That is not to say, however, that district courts will be compelled to adjudicate every such dispute. As this Court has made clear, "district courts possess discretion in determining whether and when to entertain an action under the Declaratory Judgment Act, even when the suit otherwise satisfies subject matter jurisdictional prerequisites." *Wilton* v. *Seven Falls Co.*, 515 U.S. 277, 282 (1995). Those considerations apply in patent cases just as they do in all other types of declaratory judgment actions.

Whatever the precise bounds of discretion under the Declaratory Judgment Act, however, see *Wilton*, 515 U.S. at 290, it would be inappropriate for a district court to decline to exercise jurisdiction merely on the ground that the declaratory judgment plaintiff is a licensee in good standing. To do so would be inconsistent with the reasoning of *Lear*, which is founded on the principle that the interests of federal patent law are furthered by allowing licensees to challenge the validity of patents. The *Lear* Court carefully weighed the underlying justifications for the traditional contractual doctrine of licensee estoppel against the "important public interest" in encouraging challenges to potentially invalid patents, and concluded that "the technical requirements of contract doctrine must give way before the demands of the

public interest in the typical situation involving the negotiation of a license after a patent has issued." 395 U.S. at 670-671. That determination forecloses any suggestion that vestigial notions of licensee estoppel can be employed to justify the creation of new obstacles to the adjudication of such challenges.

Beyond that, it is not necessary for the Court to determine under what circumstances a district court might decline to entertain a declaratory action by a licensee. The district court in this case had no occasion to consider that question, because *Gen-Probe* compelled it to dismiss the action. That court is in the best position to address any such discretionary matters in the first instance. See *Wilton*, 515 U.S. at 289 (vesting "district courts with discretion in the first instance, because facts bearing on the usefulness of the declaratory judgment remedy, and the fitness of the case for resolution, are peculiarly within their grasp").

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

PAUL D. CLEMENT
Solicitor General

PETER D. KEISLER
Assistant Attorney General

THOMAS G. HUNGAR
Deputy Solicitor General

DEANNE E. MAYNARD
Assistant to the Solicitor General

SCOTT R. MCINTOSH
MARK R. FREEMAN
Attorneys

JAMES A. TOUPIN
General Counsel

JOHN M. WHEALAN
Solicitor

MARY L. KELLY
JOSEPH G. PICCOLO
Associate Solicitors
United States Patent and Trademark Office

MAY 2006